Efficacy and Tolerability of a Combined 445nm and 630nm Over-the-counter Light Therapy Mask with and without Topical Salicylic Acid versus Topical Benzoyl Peroxide for the Treatment of Mild-to-moderate Acne Vulgaris

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ABSTRACT

Objective: To evaluate the efficacy and tolerance of a combined 445nm/630nm light therapy mask for the treatment of mild-to-moderate acne vulgaris with and without topical 1% salicylic acid with retinol versus 2.5% benzoyl peroxide. **Design:** A 12-week evaluator-blinded, randomized study. Subjects were randomized to be treated with the 445nm/630nm light therapy mask alone, benzoyl peroxide, or 445nm/630nm light therapy mask with topical 1% salicylic acid with retinol. **Participants:** Healthy male and female subjects 12 to 35 years old with Fitzpatrick skin types I to VI and mild-to-moderate facial acne vulgaris. **Measurements:** The primary endpoint was the change in the number of inflammatory acne lesions after 12 weeks of treatment. Secondary endpoints included the change in noninflammatory acne lesions, change in total acne lesions, change in Investigator Global Acne Assessments, and overall responder rate. **Results:** 445nm/630nm light therapy mask-treated subjects showed a 24.4-percent improvement in inflammatory acne lesions ($p<0.01$) versus 17.2 percent ($p<0.05$) and 22.7 percent ($p<0.01$) in benzoyl peroxide and 445nm/630nm light therapy mask with topical 1% salicylic acid with retinol, respectively, a 19.5-percent improvement in noninflammatory lesions ($p<0.001$) versus 6.3 and 4.8 percent for benzoyl peroxide and 445nm/630nm light therapy mask with topical 1% salicylic acid with retinol, respectively. Subjects in the 445nm/630nm light therapy mask group also achieved a 19.0-percent improvement in the Investigator Global Acne Assessment ($p<0.001$) versus 4.7 percent in benzoyl peroxide and 13.9 percent in 445nm/630nm light therapy mask with topical 1% salicylic acid with retinol ($p<0.01$). Treatments were well-tolerated overall with trends toward less early irritation in the 445nm/630nm light therapy mask group. **Conclusion:** 445nm/630nm light therapy mask appears to be a safe and effective therapy for mild-to-moderate acne. (*J Clin Aesthet Dermatol.* 2016;9(3):25–35.)

Acne vulgaris is a chronic inflammatory disease of pilosebaceous units. The major factors involved in the pathogenesis are increased sebum production, hypercornification of the pilosebaceous duct, ductal colonization with *Propionibacterium acnes,* and inflammation.[1] It remains the most commonly encountered skin disease,[2] affecting an estimated 45 million people in the United States[3] and approximately 80 to 95 percent of all individuals at some time in their lives.[2,3]

Although commonly thought to primarily affect teenagers, adolescents comprised only 36.5 percent of acne patients while adults comprised 61.9 percent.[4] It is estimated that US consumers spend $1.2 billion each year for the treatment of acne[3] with mean individual costs of $689 and ranging from $361 to $869.[4] Acne can have long-lasting psychosocial effects with a severe negative impact

DISCLOSURE: Dr. Nestor is a consultant to La Lumiere LLC, Cleveland, Ohio, and received a research grant for this study. The authors acknowledge the editorial assistance of Dr. Carl S. Hornfeldt, Apothekon, Inc., with funding provided by La Lumiere.
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on quality of life[5,6] across different races and ethnicities.[7] Depression has been reported in more than 10 percent of female acne patients.[4]

Despite the wide variety of available topical and systemic acne treatments, treatment for acne remains far from optimal.[2] In addition, prescription acne medications, such as systemic antibiotics and retinoids, can cause adverse effects (AEs) that occasionally pose significant health risks to the patient,[8,9] and the long-term use of systemic antibiotics can be a significant factor in bacterial resistance.[10] Common over-the-counter (OTC) products for the treatment of acne include topical benzoyl peroxide (BPO),[11,12] salicylic acid,[13,14] and moisturizers.[15,16] Unfortunately, patient satisfaction with treatment outcomes can be low, especially with OTC products.[17]

Light of varying wavelengths has been shown to have a therapeutic effect on a variety of skin conditions and disorders.[18–20] Blue light has been shown to have beneficial effects on acne.[21,22] This is believed to occur due to the effects of blue light on protoporphyrins with free radical formation and subsequent destruction of the cell membrane of *Propionibacterium acnes*,[23,24] which plays an important role in the etiology of acne.[25] Red light has anti-inflammatory effects[26] and has been shown to be beneficial for the treatment of inflammatory acne lesions.[27]

Several devices that employ blue light-emitting diodes (LEDs) have been developed for the treatment of acne,[28–31] which have a beneficial effect on acne lesions.[32] In addition, studies have shown the use of combined red and blue light is also very effective.[21,33] The results of a randomized, double-blind, sham-controlled study indicate the addition of red light results in significant improvements in both inflammatory and noninflammatory acne lesions.[34]

A device has been developed to provide home acne treatment using LEDs that emit both 445nm blue and 630nm red light. Designed to be worn as a mask, it provides full-face treatment during each daily 15-minute light therapy session (illuMask® Acne Light Therapy Mask; La Lumiere, LLC, Cleveland, Ohio). The objective of this 12-week, randomized, double-blind study was to evaluate the efficacy and tolerance of the combined 445nm blue/630nm red light therapy mask (MASK) for the treatment of mild-to-moderate acne vulgaris with and without topical 1% salicylic acid with retinol (MASK-SA) versus 2.5% BPO.

METHODS

Study participants. Healthy male and female subjects 12 to 35 years old with Fitzpatrick Skin Types I to VI were eligible for enrollment. Subjects were required to have mild-to-moderate facial acne vulgaris, defined as 20 to 140 total lesions, with 10 to 90 noninflammatory and 10 to 50 inflammatory facial lesions, but no nodules or cysts (Investigator's Global Assessment Score of 2, 2.5, 3, or 3.5 using the Modified Cook's Scale).[35] Each subject expressed a willingness to comply with the requirements of the study, which included avoiding excessive sun exposure and tanning beds, artificial tanning creams, and facial spray tans. The use of hats outdoors was strongly advised. Female subjects of childbearing potential received a urine pregnancy test prior to participating in the study and agreed to use a medically acceptable form of birth control during the study.

Reasons for exclusion from the study included a known allergy to any ingredients in the test products; presence of severe acne or acne conglobate; pre-existing or dormant facial dermatologic conditions, such as psoriasis, rosacea, rashes, many or severe excoriations that could interfere with the outcome of the study; use of prescription topical antibiotics, such as clindamycin or topical retinoids within the past two weeks or the use of oral retinoids within the past six months; use of oral antibiotics within the past four weeks; use of topical acne medications containing BPO or salicylic acid within the past two week; excessive facial hair, including beard, mustache or goatee, or scars that could interfere with imaging or evaluations; or participation in any other clinical study during the past four weeks.

Light therapy. The acne light therapy device uses LED technology to emit red (630nm) and blue (445nm) light. It has been cleared by the United States Food and Drug Administration for the treatment of mild-to-moderate acne (illuMask® La Lumiere, LLC., Cleveland, Ohio). The arrays of LEDs are designed as a lightweight mask that is worn by the user. Study subjects assigned to use the light mask were instructed to place the mask over the face and turn the device on. The device turns off automatically after each 15-minute treatment.

Study treatment groups. Eligible subjects were randomized in blinded fashion to undergo one of three treatments:

MASK group: Neutrogena® Ultra-Gentle Foaming Cleanser (Johnson and Johnson Consumer, Inc., New Brunswick, New Jersey) and the MASK treatment. The cleanser was used to wash the face each morning and evening. The MASK treatment was applied once daily after the facial cleansing. A non-medicated moisturizer was permitted as needed

BPO group: Neutrogena® Ultra-Gentle Foaming Cleanser and Neutrogena® Complete Acne Therapy System Overnight Acne Control Lotion (2.5% benzoyl peroxide) (Johnson and Johnson Consumer, Inc.). The cleanser was used to wash the face each morning and evening. The acne treatment was applied to the entire face in a thin layer each morning and evening. The product was allowed to dry before applying any additional facial products. A non-medicated moisturizer was permitted not more than twice daily as needed.

MASK-SA group: Neutrogena® Ultra-Gentle Foaming Cleanser and Neutrogena® All-in-1 Acne Control Facial Treatment (1% salicylic acid plus retinol) (Johnson and Johnson Consumer, Inc.) and the MASK treatment. The cleanser was used to wash the face each morning and evening. The acne treatment was applied to the entire face in a thin layer each morning. The product was allowed to dry before applying any additional facial products. The light mask treatment was applied once daily after the facial cleansing. A non-medicated moisturizer was permitted not

more than twice daily as needed. In the evening, moisturizer was not to be applied until after the mask treatment was complete.

Subjects received pre-weighed containers of their assigned test product and written and verbal instructions on their product use and were instructed to bring the product to each clinic visit. The initial product application was performed by each subject in the clinic under the supervision of trained study staff. Each subject also received a diary for recording daily product applications.

Assessments. Subjects were instructed to cleanse their face with their customary non-medicated facial cleanser and to remove all facial and eye makeup at least 30 minutes but not more than two hours prior to each clinic visit. Screening and baseline subject assessments performed during Visit 1 included medical history, enrollment criteria, and urine pregnancy test for relevant subjects. Baseline study assessments included the Investigator Global Acne Assessment (IGA) and acne counts. Full facial acne counts were performed on the forehead, left and right cheeks, chin, upper lip, and nose. Each count including inflammatory and noninflammatory lesions was repeated on Day 1, Weeks 1, 2, 4, 8, and 12 (Visits 2, 3, 4, 5, and 6), or at the time of study withdrawal and included:

Inflammatory lesions

- Papule (small, red, solid elevation <1.0cm in diameter)
- Pustule (small, circumscribed elevation of the skin containing yellow-white exudate)
- Nodule or cyst (circumscribed, elevated, solid lesion generally >1.0cm in diameter with palpable depth)

Noninflammatory lesions

- Open comedones (pigmented dilated pilosebaceous orifice, or blackhead)
- Closed comedones (tiny white papule or whitehead)

Additional assessments performed by the Investigator at each clinic visit included:

- Overall redness of inflammatory lesions
- Overall size of inflammatory lesions
- Tactile skin surface roughness
- Uneven skin tone
- Skin blotchiness
- Lack of skin clarity.

Treatment Responders were defined as individuals showing improvement in two of the three of the primary endpoints of IGA, inflammatory and noninflammatory lesions at Week 12 while Full Responders were defined as individuals showing improvement in all three primary endpoints.

A grading scale was used by the Investigator for the following objective treatment tolerance assessments: Erythema, Edema, Dryness, and Peeling. A similar grading scale was used by subjects for the following subjective treatment tolerance assessments: Burning/Stinging, Itching and Dryness/Tightness. Full-face digital images of each subject (center, 45° left, and 45° right) were obtained by a trained photographer using a VISIA-CR multi-flash imaging system (Canfield Scientific, Inc., Fairfield, New Jersey).

TABLE 1. Demographics and baseline characteristics

	N (%)
Gender	
Female	31 (30)
Male	74 (70)
Age	
12–18 years	49 (47)
19–25 years	35 (33)
26–33 years	21 (20)
Race/Ethnicity	
African-American	35 (33)
Caucasian	28 (27)
Hispanic/Latino	33 (31)
Asian	3 (3)
Pacific Islander	3 (3)
Other	3 (3)
Fitzpatrick Skin Type	
I	(3)
II	(19)
III	(15)
IV	(24)
V	(12)
VI	(27)

Study endpoints. The primary endpoint was the change in the number of inflammatory acne lesions after 12 weeks of treatment. Secondary endpoints included the change in noninflammatory acne lesions, change in total acne lesions, change in Investigator Global Acne Assessments, Overall Responder Rate, changes in size and redness of acne lesions, skin quality, and treatment tolerability.

Safety. Subjects were queried about potential AEs during each clinic visit and were encouraged to report possible AEs to the Investigator at any time. The Investigator examined the treated area at each visit for evidence of any possible treatment-related AEs.

Statistical analysis. To ensure completion of approximately 30 subjects per group, it was planned that 105 qualified subjects would be enrolled (35 per group). The intention-to-treat (ITT) population was all randomized subjects, regardless of whether they received study treatment. The per protocol (PP) population was all subjects in the ITT population for whom no major protocol violations occurred. The ITT population was used for the efficacy analysis. The assessment of safety is based on the safety population. Continuous data was summarized by treatment group using descriptive statistics. Categorical data was summarized by treatment group using frequency tables including 95% confidence intervals. Statistical testing was 2-sided and conducted at the 0.05 significance level. An analysis of means using an independent samples *t*-test and analysis of covariance (ANCOVA) were used to evaluate any difference between the baseline and total lesions on

Table 2. Efficacy endpoints

ATTRIBUTE	TREATMENT	STATISTIC	BASELINE	WEEK 1	WEEK 2	WEEK 4	WEEK 8	WEEK 12
Total inflammatory lesion count	MASK	Mean (SD), n	19.7 (7.8), 35	18.1 (7.5), 33	17.0 (7.0), 33	15.3 (5.9), 31	13.6 (6.7), 28	12.9 (6.9), 27
		Mean % Baseline Change	N/A	-7.6	-9.2	-15.1**	-23.9***	-24.4**
	BPO	Mean (SD), n	18.5 (9.7), 35	18 (10.5), 32	16.2 (9.1), 32	14.6 (7.5), 33	13.6 (7.3), 32	14.7 (9.4), 33
		Mean % Baseline Change	N/A	-1.4	-5.3	-11	-19.1**	-17.2*
	MASK-SA	Mean (SD), n	18.3 (8.8), 35	18.5 (9.3), 32	16.0 (7.6), 31	14.3 (7.0), 32	14.8 (7.), 32	13.26 (6.9), 32
		Mean % Baseline Change	N/A	6.9	-9.7	-19.5***	-14.6*	-22.7**
Total non-inflammatory lesion count	MASK	Mean (SD), n	34.8 (16.0), 35	32.6 (17.5), 33	32.0 (17.8), 33	30.0 (17.7), 31	27.1 (16.1), 28	25.7 (16.8), 27
		Mean % Baseline Change	N/A	-7.5	-5.9	-10.9	-14.6	-19.5***
	BPO	Mean (SD), n	31.6 (15.8), 35	32.1 (17.1), 32	30.7 (19.9), 32	29.6 (19.2), 33	27.8 (17.1), 32	29.4 (19.4), 33
		Mean % Baseline Change	N/A	4.5	-1.2	-4.3	-7.6	-6.3
	MASK-SA	Mean (SD), n	26.0 (12.1), 35	26.2 (13.4), 32	25.3 (16.4), 31	24.6 (15.4), 32	24.1 (18.1), 32	24.3 (17.1), 32
		Mean % Baseline Change	N/A	3.7	-2.6	-1.9	-7.8	-4.8
Total lesion count	MASK	Mean (SD)	54.5 (18.9), 35	50.6 (20.0), 33	49.0 (20.5), 33	45.2 (19.8), 31	40.8 (18.5), 28	38.6 (20.8), 27
		Mean % Baseline Change	N/A	-7.6*	-8	-13.5**	-19.5***	-22.8**
	BPO	Mean (SD)	50.2 (21.0), 35	50.1 (22.9), 32	46.9 (23.8), 32	44.1 (22.4), 33	41.4 (20.4), 32	44.0 (23.6), 33
		Mean % Baseline Change	N/A	1.7	-4.9	-9.8**	-14.46**	-11.4*
	MASK-SA	Mean (SD)	44.3 (13.9), 35	44.7 (17.4), 32	41.4 (19.9), 31	39.0 (17.5), 32	38.9 (22.4), 32	37.5 (21.9), 32
		Mean % Baseline Change	N/A	3.6	-6.4	-10.2	-12.7	-15.3
Investigator Global Assessment (IGA)[a]	MASK	Mean (SD), n	2.7 (0.5), 35	2.6 (0.5), 33	2.6 (0.6), 33	2.5 (0.5), 31	2.3 (0.6), 28	2.1 (0.5), 27
		Mean % Baseline Change	N/A	-3.1*	-4.5**	-3.8	-12.4**	-19.0***
	BPO	Mean (SD), n	2.4 (0.5), 35	2.47 (0.5), 32	2.5 (0.5), 32	2.3 (0.5), 33	2.2 (0.6), 32	2.3 (0.6), 33
		Mean % Baseline Change	N/A	1.7	4.3	-3.4	-7.5*	-4.7
	MASK-SA	Mean (SD), n	2.5 (0.5), 35	2.5 (0.5), 32	2.5 (0.5), 31	2.3 (0.5), 32	2.2 (0.6), 32	2.1 (0.6), 32
		Mean % Baseline Change	N/A	3	0.9	-7.3*	-7.2	-13.9**

[a]Scale: 0=Clear, 1=Almost Clear, 2=Mild, 3=Moderate, 4=Severe, 5=Very Severe. * denotes *p*=0.05, ** denotes *p*=0.01, *** denotes *p*=0.001.

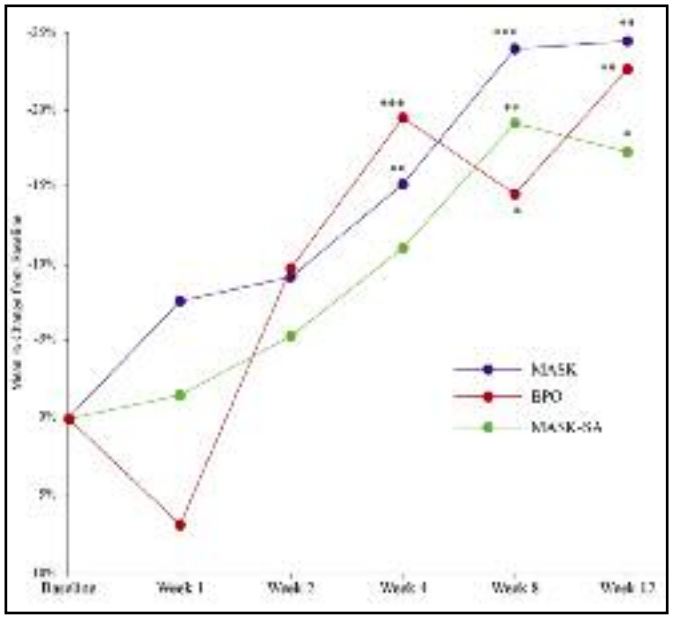

Figure 1. Change in inflammatory acne lesions. MASK=Skin cleanser and the light mask treatment; BPO=Skin cleanser and 2.5% benzoyl peroxide lotion; MASK-SA=Skin cleanser and 1% salicylic acid + retinol and light mask treatment. MASK-treated subjects achieved 24.4% improvement in inflammatory skin lesions at Week 12.
* denotes p=0.05, ** denotes p=0.01, *** denotes p=0.001

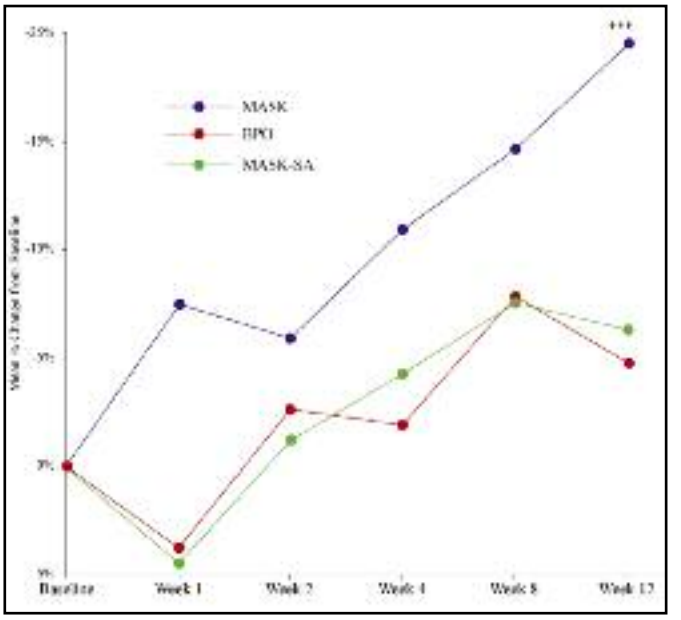

Figure 2. Change in noninflammatory acne lesions. MASK:=Skin cleanser and the light mask treatment; BPO=Skin cleanser and 2.5% benzoyl peroxide lotion; MASK-SA=Skin cleanser and 1% salicylic acid + retinol and light mask treatment. MASK-treated subjects in Group A achieved significant improvements in noninflammatory acne lesions (19.5%).
*** denotes p=0.001

Day 84. The primary analysis was completed using a chi-square assessment of relative risk and odds ratios. Tolerance and efficacy data were evaluated for all ITT subjects who were assigned a test product and had baseline and at least one post-baseline evaluation. AEs were summarized for all subjects who received a test product.

Ethics. Each subject or their parent or guardian provided informed consent prior to participating in any treatment-related activities. The protocol and related documents used in this study were approved by a commercial institutional review board (USIRB 2014 CCCR/03: U.S. Investigational Review Board, Inc., Miami, Florida). Subjects also signed a photographic release, which allows the study sponsor to use and distribute the subject photos for education and information purposes, promotional purposes, and publication of scientific work.

RESULTS

Demographics. Thirty-five subjects were enrolled into each group (N=105) of which 92 (88%) completed the trial in the MASK (n=27), BPO (n=33), and MASK-SA (n=32) groups. The most common reason for not completing the study was being unable to comply with visit schedule (n=8). The demographics and baseline characteristics of all enrolled subjects are summarized in Table 1.

Primary endpoint. The MASK group showed the greatest improvement in inflammatory acne lesions, becoming significant at Week 4 and reaching 24.4-percent improvement at Week 12 (p<0.01) (Table 2, Figure 1). The BPO group showed a 6.9-percent worsening at Week 1, but significant improvement by Week 8. MASK-SA showed steady improvement, which became significant at Week 8.

Secondary endpoints. ***Noninflammatory lesion counts.*** Only the MASK Group showed an improvement in noninflammatory lesions at all time-points, becoming significant at Week 12 (19.5% improvement, p<0.001) (Figure 2). The BPO and MASK-SA groups showed 4.5 and 3.7-percent worsening in noninflammatory lesion counts at Week 1, respectively, but achieved 6.3 and 4.8-percent improvement by Week 12.

Total lesion counts (inflammatory and noninflammatory). When inflammatory and noninflammatory acne lesions were combined, the MASK group showed significant improvement at Weeks 1, 4, 8, and 12 (Figure 3). The BPO and MASK-SA groups showed a 1.7 and 3.6-percent worsening at Week 1, respectively, but the BPO group showed significant improvement at Weeks 4, 8, and 12. The MASK-SA group did not achieve significant improvements at any time point.

Investigator Global Acne Assessment. Subjects in the MASK group achieved significant improvements in IGA scores at Weeks 1, 2, 8, and 12 (Figure 4). The BPO and MASK-SA groups showed significant worsening in IGA scores at Weeks 1 and 2. The BPO group showed significant improvement only at Week 8 and the MASK-SA group showed improvement at Weeks 4 and 12. Scores for individual improvement attributes are summarized in Table 3.

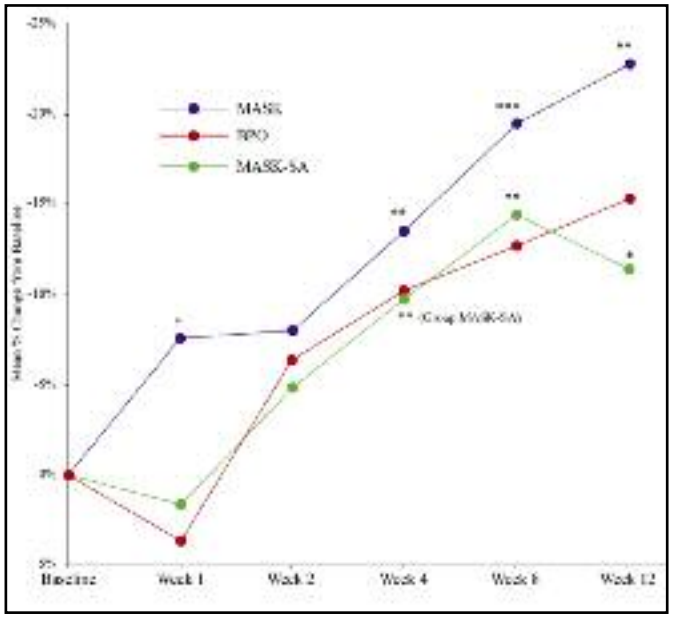

Figure 3. Change in total acne lesions. MASK=Skin cleanser and the light mask treatment; BPO=Skin cleanser and 2.5% benzoyl peroxide lotion; MASK-SA=Skin cleanser and 1% salicylic acid + retinol and light mask treatment. MASK-treated subjects achieved a 22.8% improvement in total acne lesion counts.
* denotes p=0.05, ** denotes p=0.01, *** denotes p=0.001

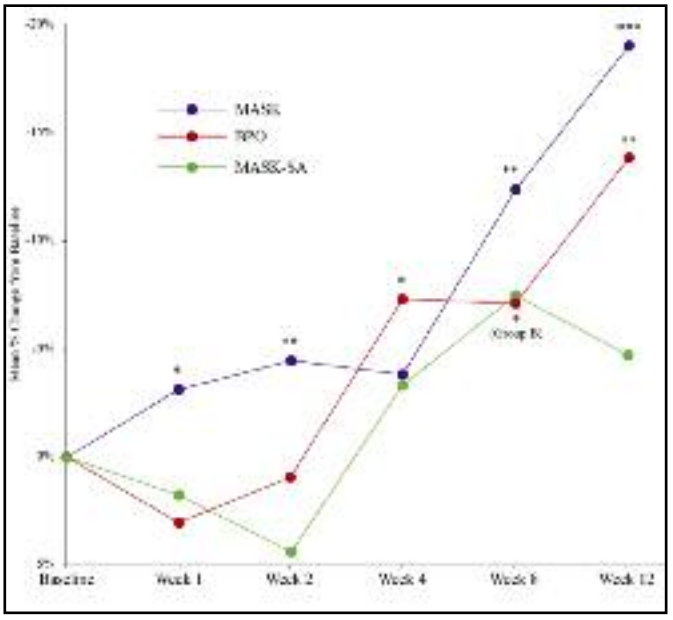

Figure 4. Change in Investigator Global Acne Assessment. MASK=Skin cleanser and the light mask treatment; BPO=Skin cleanser and 2.5% benzoyl peroxide lotion; MASK-SA=Skin cleanser and 1% salicylic acid + retinol and light mask treatment. MASK-treated subjects achieved a 19.0% improvement in change in Investigator Global Acne Assessment scores.
* denotes p=0.05, ** denotes p=0.01, *** denotes p=0.001

Overall responder rate. Subjects in the MASK group achieved the greatest percent of Responders (77.8%) and Full Responders (66.7%) followed by the BPO and MASK-SA groups, respectively (Figure 5).

Tolerability. Objective (Investigator) and Subjective (subject) ratings of product tolerance are summarized in Tables 4 and 5. Overall, all three treatments appear to have been well-tolerated. There were no reports of AEs or serious AEs.

DISCUSSION

With respect to the primary endpoint, subjects in all three treatment groups achieved significant improvements in the number of inflammatory acne lesions; however, subjects in the MASK group, which were treated with the light mask alone achieved the greatest improvement, reaching 24 percent at Week 12. Although subjects treated with 2.5% BPO (BPO group) showed a substantial worsening in inflammatory lesions at Week 1, significant improvement was seen by Week 4. Subjects treated with 1% salicylic acid/retinol plus light mask (MASK-SA group) did not show significant improvement until Week 8.

With respect to secondary endpoints, only subjects in the MASK group achieved a significant decrease in noninflammatory acne lesions. Subjects in the MASK group also achieved significant reductions in total lesion counts as early as Week 1 of treatment and reaching a nearly 23-percent reduction by Week 12 while subjects in the BPO and MASK-SA groups achieved only 11 and 15-percent improvement, respectively. Subjects in the MASK group also achieved immediate and sustained improvements in IGA assessments, reaching 19-percent improvements at Week 12 while the BPO and MASK-SA groups achieved only 5 and 14-percent improvements, respectively. Based on IGA assessments, the Responder Rate for the MASK group was 77.8 percent versus 55 percent and 63 percent for the BPO and MASK-SA groups, respectively, and Full Responder Rate for the MASK group was 67 percent versus 27 percent and 47 percent for the BPO and MASK-SA groups, respectively.

Subjects in all three groups showed minor improvements or no change in overall inflammatory lesion redness, inflammatory lesion size, tactile surface roughness, uneven skin tone, skin blotchiness, and lack of skin clarity. There were no significant differences in treatment tolerability, but there was a trend toward improved Tightness/Dry Feeling among subjects in the MASK group while those in the BPO groups reported worsening from Weeks 1 to 4. Overall, the use of the light mask alone appeared to trend toward superiority to 2.5% BPO alone or when combined with 1% salicylic acid and retinol. Importantly, these beneficial effects appear across a wide range of subject ages, races, and Fitzpatrick skin types.

Light therapy has become widely used for the treatment of acne. Although blue light has a somewhat limited depth of skin penetration,[36] it is the most effective visible wavelength for treating *P. acnes* because it produces the strongest photoactivation of endogenous porphyrins.[23,24] In

Table 3. Secondary endpoints

ATTRIBUTE	TREATMENT	STATISTIC	BASELINE	WEEK 1	WEEK 2	WEEK 4	WEEK 8	WEEK 12
Overall inflammatory lesion redness[a]	MASK	Median (min, max), n	4.0 (0, 9), 35	4.0 (0, 9), 33	4.0 (0, 9), 33	4.0 (0, 9), 31	4.0 (0, 9), 28	3.0 (0, 9), 27
	BPO	Median (min, max), n	5.0 (0, 8), 35	4.5 (0, 8), 32	4.0 (0, 8), 32	3.0 (0, 8), 33	3.5 (0, 8), 32	4.0 (0, 8), 33
	MASK-SA	Median (min, max), n	4.0 (0, 8), 35	4.0 (0, 8), 32	4.0 (0, 8), 31	4.0 (0, 8), 32	4.0 (0, 8), 32	3.5 (0, 8), 32
Overall inflammatory lesion size[a]	MASK	Median (min, max), n	5.0 (2, 8), 35	5.0 (2, 8), 33	5.0 (2, 8), 33	4.0 (2, 7), 31	4.0 (2, 8), 28	4.0 (2, 8), 27
	BPO	Median (min, max), n	4.0 (2, 8), 35	4.0 (2, 8), 32	4.0 (2, 8), 32	4.0 (2, 8), 33	4.0 (2, 8), 32	4.0 (1, 9), 33
	MASK-SA	Median (min, max), n	4.0 (2, 8), 35	4.0 (2, 8), 32	40 (2, 8), 31	4.0 (2, 8), 32	4.0 (2, 8), 32	3.0 (2, 8), 32
Tactile surface roughness[a]	MASK	Median (min, max), n	2.0 (0, 10), 35	2.0 (1, 10), 33	2.0 (0, 10), 33	2.0 (0, 10), 31	2.0 (0, 10), 28	2.0 (0, 10), 27
	BPO	Median (min, max), n	3.0 (0, 8), 35	2.0 (0, 8), 32	2.0 (0, 9), 32	2.0 (0, 8), 33	2.0 (0, 8), 32	2.0 (0, 8), 33
	MASK-SA	Median (min, max), n	2.0 (0, 9), 35	2.0 (0, 8), 32	2.0 (0, 8), 31	2.0 (0, 7), 32	2.0 (0, 7), 32	2.0 (0, 7), 32
Uneven skin tone[a]	MASK	Median (min, max), n	4.0 (1, 8), 35	4.0 (1, 8), 33	4.0 (1, 8), 33	4.0 (1, 8), 31	4.0 (1, 8), 28	3.0 (1, 8), 27
	BPO	Median (min, max), n	4.0 (1, 8), 35	3.5 (1, 8), 32	4.0 (1, 8), 32	4.0 (1, 7), 31	4.0 (1, 7), 32	3.0 (1, 7), 33
	MASK-SA	Median (min, max), n	3.0 (1, 9), 35	3.0 (1, 9), 32	3.0 (1, 9), 31	3.0 (1, 9), 32	3.0 (1, 9), 32	3.0 (1, 9), 32
Skin blotchiness[a]	MASK	Median (min, max), n	1.0 (0, 8), 35	2.0 (0, 8), 33	2.0 (0, 8), 33	1.0 (0, 9), 31	1.0 (0, 8), 28	1.0 (0, 8), 27
	BPO	Median (min, max), n	1.0 (0, 7), 35	1.0 (0, 7), 32	1.0 (0, 7), 32	1.0 (0, 7), 33	1.0 (0, 6), 32	1.0 (0, 6), 33
	MASK-SA	Median (min, max), n	2.0 (0, 9), 35	2.0 (0, 9), 32	2.0 (0, 8), 31	2.0 (0, 8), 32	2.0 (0, 7), 32	2.0 (0, 7), 32
Lack of skin clarity[a]	MASK	Median (min, max), n	6.0 (2, 9), 35	6.0 (2, 8), 33	5.0 (2, 8), 33	5.0 (2, 7), 31	4.0 (2, 8), 28	4.0 (2, 8), 27
	BPO	Median (min, max), n	4.0 (3, 9), 35	4.0 (3, 8), 32	4.0 (3, 8), 32	4.0 (3, 8), 33	4.0 (2, 7), 32	4.0 (0, 9), 33
	MASK-SA	Median (min, max), n	4.0 (2, 8), 35	4.0 (2, 8), 32	4.0 (2, 9), 31	4.0 (2, 8), 32	4.0 (2, 7), 32	3.0 (1, 7), 32

[a]Scale 0–9, with 0=none, 1–3=mild, 4–6=moderate, 7–9=severe

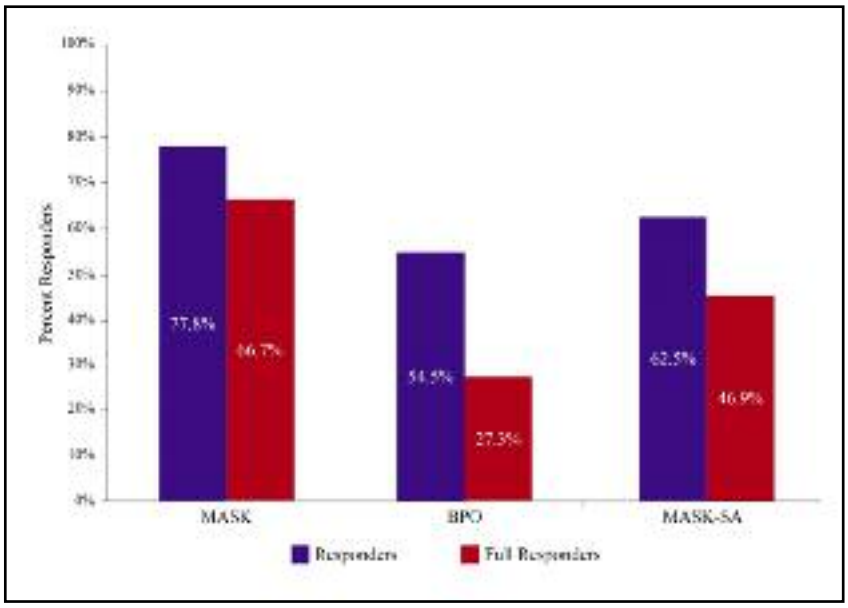

Figure 5. Responder analysis. MASK=Skin cleanser and the light mask treatment; BPO=Skin cleanser and 2.5% benzoyl peroxide lotion; MASK-SA=Skin cleanser and 1% salicylic acid + retinol and light mask treatment. Responders were subjects with improvements in two of three primary endpoints of IGA, inflammatory, or noninflammatory lesions at Week 12. Full Responders were subjects with improvements in all three primary endpoints at Week 12.

addition to deeper penetration,[27] red light also has anti-inflammatory effects[26] and is beneficial for the treatment of inflammatory acne lesions.[27] Thus, greater clinical improvement is associated with combined red and blue light therapy.

The results of the present study compare favorably with other studies, which used 415nm blue/633nm red LEDs,[33,37,38] 420nm blue/660nm red LEDs,[34] and 415nm blue/660nm red LEDs.[39] Two eight-week studies reported 34.28 and 77.93-percent improvements in noninflammatory and inflammatory lesions, respectively,[37] and 48.8-percent improvements in noninflammatory lesions.[33] Three 12-week studies reported 54 and 77-percent improvements in noninflammatory and inflammatory lesions, respectively,[34] and overall improvements of 76 percent[39] and 81 percent.[38] One other comparative study also reported that blue/red light therapy was superior to 5% BPO cream.[39]

It should be noted that most of these studies were small, enrolling only 17 to 35 subjects[33,34,37,38] and importantly, these studies were required to expose treated subjects with blue and red light sequentially from different light sources. To the authors' knowledge, the device used in the present study is the only available device that provides the convenience of simultaneous exposure to blue and red light.

CONCLUSION

The results of this 12-week evaluator-blinded, randomized study demonstrated the effectiveness of a LED device emitting red (630nm) and blue (445nm) light for the treatment of mild-to-moderate acne vulgaris across a range of subject ages, racial backgrounds, and skin types. There were no reports of AEs. This device has received FDA clearance for home use.

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Table 4. Tolerability—objective Reporting

ATTRIBUTE	TREATMENT	STATISTIC	BASELINE	WEEK 1	WEEK 2	WEEK 4	WEEK 8	WEEK 12
Erythema[a]	MASK	Mean (SD), n	0.5 (0.7), 35	0.6 (0.7), 33	0.5 (0.7), 33	0.6 (0.8), 31	0.5 (0.7), 28	0.6 (0.8), 27
		Mean % Baseline Change	N/A	0	0	0	0	0
	BPO	Mean (SD), n	0.5 (0.6), 35	0.4 (0.6), 32	0.4 (0.6), 32	0.4 (0.6), 33	0.3 (0.6), 32	0.4 (0.6), 33
		Mean % Baseline Change	N/A	-0.1	-0.1	-0.1	-0.1	-0.1
	MASK-SA	Mean (SD), n	0.5 (0.6), 35	0.5 (0.6), 32	0.5 (0.6), 31	0.5 (0.6), 32	0.5 (0.6), 32	0.4 (0.6), 32
		Mean % Baseline Change	N/A	0	0	0	0	-0.1
Dryness/ scaling[a]	MASK	Mean (SD), n	0.1 (0.4), 35	0.2 (0.4), 33	0.1 (0.3), 33	0.1 (0.3), 31	0.0 (0), 28	0.1 (0.3), 27
		Mean % Baseline Change	N/A	0	0	0	-0.1	0
	BPO	Mean (SD), n	0.2 (0.5), 35	0.1 (0.3), 32	0.2 (0.5), 32	0.2 (0.4), 33	0.1 (0.3), 32	0.1 (0.3), 33
		Mean % Baseline Change	N/A	-0.1	0	0	-0.1	-0.1
	MASK-SA	Mean (SD), n	0.1 (0.4), 35	0.2 (0.4), 32	0.3 (0.5), 31	0.2 (0.4), 32	0.03 (0.28), 32	0.06 (0.4), 32
		Mean % Baseline Change	N/A	0.1	0.2	0	-0.1	-0.1
Peeling[a]	MASK	Mean (SD)	0.1 (0.2), 35	0.1 (0.3), 33	0.03 (0.2), 33	0.03 (0.2), 31	0.04 (0.2), 28	0.04 (0.2), 27
		Mean % Baseline Change	N/A	0.1	0	0	0	0
	BPO	Mean (SD)	0.1 (0.4), 35	0.03 (0.2), 32	0.03 (0.2), 32	0.09 (0.3), 33	0.03 (0.2), 32	0.03 (0.2), 33
		Mean % Baseline Change	N/A	-0.1	-0.1	0	-0.1	-0.1
	MASK-SA	Mean (SD)	0.1 (0.4), 35	0.1 (0.3), 32	0.2 (0.5), 31	0.1 (0.3), 32	0.0 (0.0), 32	0.1 (0.4), 32
		Mean % Baseline Change	N/A	0	0.1	0	-0.1	0
Edema[a]	MASK	Mean (SD), n	0.0 (0), 35	0.0 (0), 33	0.0 (0), 33	0.0 (0), 31	0.0 (0), 28	0.0 (0), 27
		Mean % Baseline Change	N/A	0	0	0	0	0
	BPO	Mean (SD), n	0.0 (0), 35	0.0 (0), 32	0.0 (0), 31	0.0 (0), 33	0.0 (0), 32	0.0 (0), 33
		Mean % Baseline Change	N/A	0	0	0	0	0
	MASK-SA	Mean (SD), n	0.0 (0), 35	0.0 (0), 32	0.0 (0), 31	0.0 (0), 32	0.0 (0), 32	0.0 (0), 32
		Mean % Baseline Change	N/A	0	0	0	0	0

[a]Scale: 0=None, 1=Mild, 2=Moderate, 3=Severe

Table 5. Tolerability—subjective reporting

ATTRIBUTE	TREATMENT	STATISTIC	BASELINE	WEEK 1	WEEK 2	WEEK 4	WEEK 8	WEEK 12
Burning/ stinging[a]	MASK	Mean (SD), n	0.06 (0.2), 35	0.12 (0.5), 33	0 (0), 33	0 (0), 31	0 (0), 28	0.04 (0.2), 27
		Mean % Baseline Change	N/A	0.1	-0.1	-0.1	-0.1	0
	BPO	Mean (SD), n	0.06 (0.2), 35	0 (0), 32	0 (0), 32	0 (0), 33	0.06 (0.4), 32	0.06 (0.2), 33
		Mean % Baseline Change	N/A	0	0	0	0	0
	MASK-SA	Mean (SD), n	0 (0), 35	0.13 (0.4), 32	0.29 (0.6), 31	0.03 (0.2), 32	0.03 (0.2), 32	0.06 (0.3), 32
		Mean % Baseline Change	N/A	0.1	0.3	0	0	0.1
Itching[a]	MASK	Mean (SD), n	0.0 (0), 35	0.06 (0.2), 33	0.0 (0), 33	0.0 (0), 31	0.07 (0.48), 28	0.0 (0), 27
		Mean % Baseline Change	N/A	0.1	0	0	0.1	0
	BPO	Mean (SD), n	0.06 (0.2), 35	0.06 (0.4), 32	0.0 (0), 32	0.0 (0), 33	0.06 (0.3), 32	0.09 (0.4), 33
		Mean % Baseline Change	N/A	0	-0.1	-0.1	0	0
	MASK-SA	Mean (SD), n	0.0 (0), 35	0.03 (0.2), 32	0.03 (0.2), 31	0.03 (0.2), 32	0.06 (0.3), 32	0.03 (0.2), 32
		Mean % Baseline Change	N/A	0	0	0	0.1	0
Tightness/dry feeling[a]	MASK	Mean (SD)	0.3 (0.5), 35	0.3 (0.6), 33	0.2 (0.4), 33	0.1 (0.3), 31	0.3 (0.5), 28	0.1 (0.3), 27
		Mean % Baseline Change	N/A	0.1	0	-0.1	0	-0.1
	BPO	Mean (SD)	0.2 (0.4), 35	0.2 (0.4), 32	0.3 (0.5), 32	0.2 (0.4), 33	0.2 (0.5), 32	0.2 (0.5), 33
		Mean % Baseline Change	N/A	0	0.1	0	-0.1	0
	MASK-SA	Mean (SD)	0.5 (0.7), 35	0.7 (0.6), 32	0.8 (0.7), 31	0.6 (0.7), 32	0.4 (0.6), 32	0.3 (0.5), 32
		Mean % Baseline Change	N/A	0.2	0.3	0.1	-0.1	-0.2

[a]Scale: 0=None, 1=Mild, 2=Moderate, 3=Severe

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